

REMARKS

Claims 1-184 are currently pending in this application.

1. Status of the Claims

Claims 1-184 are pending in this application. Claims 2-3, 11-16, 26-29, 33-36, 45, 49-53, 55, 62, 69, 76-78, 85, 92-94, 99-100, 108-112, 122-128, 131, 138, 145, 152-154, 161, 166, and 168-184 were amended as to various matters of form in order to further clarify the invention.

2. 35 U.S.C. § 112 Rejection

Claims 3, 16, 27, 29, 36, 49, 51, 99 and 100 were rejected under 35 U.S.C. §112 for failing to set clearly forth the metes and bounds of the patent protection desired. Claims 2, 3, 16, 27, 29, 36, 49, 51, 99, 100 and 124 were amended to eliminate the "such as" language and more clearly define the patent protection desired. Applicants respectfully request that the 35 U.S.C. §112 rejection be withdrawn.

3. 35 U.S.C. §103(a) Rejection

Claims 1-184 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,981,687 (Fregly) in view of U.S. Patent No. 5,114,732 (Stray-Gundersen), Japanese Patent to Ostuka (B2), British Patent No. 1,252,781 (Bradley), Japanese Patent No. 05-27904 (Ostuka), and U.S. Patent No. 6,485,764 (Robergs). Applicants respectfully traverse these objections. Additionally, Examiner discusses the references Greenleaf and Fischer '972 but does not cite the patent number for either of these references. For the purposes of this paper, applicants assume that Greenleaf is U.S. Patent No. 5,447,730 (Greenleaf) and Fischer '972 is European Patent No. 0587972 (Fischer). Additionally, Examiner cites Japanese Patent No. 05-27904 to Ostuka. Applicants respectfully submit that the proper citation is Japanese Patent No. 05-276904 to Ostuka. For the purposes of this paper, Applicants assume that the Examiner intended to reference Japanese Patent No. 05-279604 (Ostuka). Claims 15, 26, 28, 35, 45, 50, 55, 62, 69, 78, 85, 93, 112, 122, 123, 131, 138, 145, 154, 161, and

169-184 were amended to further clarify the invention. The Examiner is requested to confirm each of the foregoing assumptions.

a. Fregly In Combination With The Other References Does Not Teach Or Suggest A Beverage That Provides Superior Rehydration Through Increased Fluid Retention And Promoting Voluntary Fluid Consumption

Fregly does not teach or suggest a beverage with the claimed amounts of sodium, potassium, and chloride. Rather, Fregly discloses a beverage between 1 and 5 mEq/L of potassium, between 15 and 30 mEq/L of sodium, and no chloride. The amounts currently claimed is higher, i.e. at least 30 mEq/L of sodium and at least 8 mEq/L of potassium.

The levels of sodium, potassium, chloride, and other electrolytes as claimed, are optimized to address the adverse physiological effects of physical exertion without including stimulants or other chemical compounds which may have acute effects such as gastrointestinal distress. Figures 1-35 illustrate the extensive data that has been collected to demonstrate that the claimed combination of electrolytes promotes rehydration and sensory properties. More specifically, Figure 9 shows that urine loss during physical exertion recovery time decreases with the claimed formulations and Figure 10 shows that fluid retention increases during recovery time with the claimed formulations. Additionally, Figure 15 demonstrates that the fluid retention during extended recovery times is higher for the claimed formulations than for other known beverages that are consumed during and following physical exertion.

Furthermore, Fregly does not teach or suggest a beverage that provides superior rehydration by addressing several mechanisms affecting rehydration, such as fluid retention and voluntary fluid consumption. Rather, Fregly addresses the maintenance of blood volume through a beverage comprising electrolytic compounds and glycerol or any derivative of glycerol. See *Fregly* at col. 4, ln 55 - col. 5, ln 1. As demonstrated in Figures 3 and 4 of *Fregly*, increases in body temperature occur more slowly during exertion and cardiac output is sustained. See *Fregly*, Figs. 3-4; col. 6, lns. 43-66.

Additionally, Fregly does not teach or suggest any other methods for rehydration, such as through fluid retention and voluntarily fluid consumption. The electrolytes are not optimized to promote fluid retention and voluntarily fluid consumption as in the present invention, but rather are included in no required specific amount. The electrolytes may be added to the beverage in broad ranges, rather than as a specific and optimized amount that promotes fluid retention and voluntary fluid consumption as in the present invention. The present invention optimizes the amount of electrolytes in the beverage in order to enhance rehydration through the mechanisms of fluid retention and voluntary fluid consumption. See *Specification*, paragraphs [0012]-[0013]. As such, Fregly does not teach or suggest a beverage composition that aids in rehydration by stimulating voluntary fluid consumption and increasing fluid retention.

The foregoing basic deficiencies of Fregly are not provided by the other references pursuant to the requirements of §103. The Examiners combinations of references is a classic and impermissible instance of a hindsight reconstruction of the claimed invention. For example, the Office Action retroactively picks and chooses various disparate elements without any teaching or suggestion for modification or combination. As explained in greater detail below, the presently claimed invention provides advantages that are not taught by or inherent in the cited art.

The combination of electrolytes and osmolality of the presently claimed invention provides significant advantages that are not taught by the prior art. The claimed invention promotes greater fluid retention and voluntary fluid consumption. The level of sodium, chloride, and potassium are optimized so as to maximize rehydration without compromising the sensory properties of the beverage. See paragraph [0055].

Specifically, improved voluntary fluid consumption of the claimed formulations were shown. The formulation was favored over other sodium levels for the beverage in terms of voluntary fluid consumption. The “salty” beverage was found to become more palatable during and after exercise compared to at rest. This in turn allowed dehydration to be abated to a higher degree. See paragraph [0057].

Furthermore, the claimed invention was shown to promote fluid retention. Experimental results demonstrated that the claimed invention promotes greater fluid

retention and outperformed other formulations in attenuating fluid loss in the form of urine. See paragraph [0058]. Furthermore, as illustrated in Figure 15, the presently claimed invention promotes much greater fluid retention over the prior art. Figure 27 elaborates on this showing of greater fluid retention by illustrating the percent fluid retained as a percentage of the volume ingested during recovery time for various formulations within the prior art.

As illustrated, the claimed invention promotes greater fluid retention and provides a specific advantage that is not found within the prior art. The exact combination of electrolytes such as sodium, potassium, and chloride in the present invention has been optimized to promote enhanced fluid retention. As such, the Examiner cannot perform a hindsight reconstruction from elements that happen to exist in isolated instances within the prior art. Rather, it is the combination of claimed electrolytes that is the present invention. The specific claimed combinations show explicit advantages over the prior art where there is no suggestion that the claimed electrolyte combinations would demonstrate these advantages. As such, there is no motivation to combine these references, and a hindsight reconstruction of the prior art is not permissible.

i. Stray-Gundersen

Stray-Gundersen, alone or in combination with Fregly, does not teach or suggest a beverage with an amount of electrolytes that has been optimized in order to enhance rehydration through the mechanisms of fluid retention and voluntary fluid consumption. While Stray-Gundersen does disclose a beverage containing electrolyte ions that fall within the range of the claimed invention, such as potassium, phosphate and chloride, it also discloses that the beverage has a low osmolality. Furthermore, Stray-Gundersen states that "[o]ne important aspect of the present invention [of Stray-Gundersen] is to provide a hypotonic beverage that has a rapid gastric emptying rate." *Stray-Gundersen*, col. 7, Ins. 38-40. Additionally, the hypotonicity of the beverage of Stray-Gundersen is controlled by the amounts of electrolytes, such that the beverage maintains an osmolality that is lower than that of blood serum. *Id.* at Ins. 40-60.

The Stray-Gundersen beverage functions by allowing the beverage to quickly empty from the stomach, and hypotonic beverages empty much faster than isotonic beverages. The importance of the hypotonicity of the beverage of Stray-Gundersen, teaches away from the isotonic beverage of the present invention. Teaching away is a *per se* demonstration of a lack of prima facie obviousness. *In re Dow Chemical*, 837 F.2d 469 (Fed. Cir. 1988).

Additionally, neither Stray-Gundersen nor Fregly addresses rehydration through the mechanisms of fluid retention and voluntary fluid consumption. The present invention contains optimized amounts of electrolytes that promotes both fluid retention and stimulates voluntary fluid consumption. *See Figures 22-27; Specification* paragraphs [0056]-[0062]. As such, Stray-Gundersen in combination with Fregly, do not teach or suggest a beverage composition that aids in rehydration by stimulating voluntary fluid consumption and increasing fluid retention.

ii. Reference B2

B2 discloses the use of from 47.5-52 mEq/L sodium and 47.5 mEq/L of chloride. This is a much higher amount of chloride than in the present invention. The amount of chloride of the present invention is limited to 10-20 mEq/L in order to avoid negative sensory ratings which would not stimulate voluntary fluid consumption. An experiment was conducted in which the initial negative sensory rating was higher with higher amounts of chloride. *See Specification*, paragraph [0061]. This negative sensory rating illustrates that the consumer would not voluntarily consume the amounts of B2 as they would consume the amounts of the claimed invention.

Furthermore, by containing more than double the amount of chloride of the current invention, reference B2 is specifically teaching away from the optimized lower amounts of chloride of the present invention. Teaching away is a *per se* demonstration of a lack of prima facie obviousness. *In re Dow Chemical*, 837 F.2d 469 (Fed. Cir. 1988). As such, the B2 reference does not provide a beverage composition that will stimulate voluntary fluid consumption as in the present invention, and the B2 reference in combination with Fregly and Stray-Gundersen does not teach or suggest a beverage

composition that aids in rehydration by stimulating voluntary fluid consumption and increasing fluid retention.

iii. Greenleaf

Greenleaf does disclose a beverage with an osmolality of 270 mOsmol, and another beverage in the range of 285-300 mOsmol. However, Greenleaf is addressing fluid absorption rather than the functions of the present invention which is to stimulate voluntary fluid consumption and promote fluid retention. Thus, there is no motivation to combine Greenleaf with Fregley, Stray-Gundersen or Reference B2 to have a beverage that stimulates voluntary fluid consumption and promotes fluid retention. As such, Greenleaf in combination with the other references does not teach or suggest a beverage composition that aids in rehydration by stimulating voluntary fluid consumption and promoting fluid retention.

iv. Otsuka

Otsuka discloses a beverage utilizing 15-50 mEq/L of KCl. The electrolytes of Otsuka are included as a medium for the consumer to easily obtain and replenish the body with the electrolytes. The amounts of electrolytes have not been optimized in order to stimulate voluntary fluid consumption and promote fluid retention as in the present invention. There is no motivation to combine Otsuka with the other cited references. As such, Otsuka in combination with the other references does not teach or suggest a beverage composition that aids in rehydration by stimulating voluntary fluid consumption and increasing fluid retention.

v. Fischer

Fischer discloses the use of several minerals/electrolytes in a beverage composition that also contains 1-14% sugar. However, the minerals are added for the purpose of replenishing the minerals within the body, and not in order to stimulate voluntary fluid consumption or promote fluid retention. The specific combination of electrolytes of Fischer or use of the beverage provides no motivation to combine Fischer with the other cited references. As such, Fischer in combination with the other cited references, does not teach or suggest a beverage composition that aids in rehydration by stimulating voluntary fluid consumption and increasing fluid retention.

vi. Bradley

Bradley discloses the use of sodium and chloride, but only up to 4.7 mEq/L potassium, which is much lower than the potassium amount of more than 8 mEq/L. The Examiner has incorrectly interpreted paragraph [0009] of Applicants' specification to mean that sodium and potassium can be substituted for each. Rather, paragraph [0009] provides that sodium and chloride ions favor the filling of the extracellular compartments of a cell and may be interchanged. Potassium and magnesium have the same relationship with each other as both favor intracellular hydration. As such, potassium and sodium are not interchangeable as sodium favors extracellular hydration and potassium favors intracellular hydration.

Furthermore, there is no motivation to combine Bradley with the other cited references. This is a hindsight reconstruction of elements within the prior art. As such, Bradley in combination with the other cited references, does not teach or suggest a beverage composition that aids in rehydration by stimulating voluntary fluid consumption and promoting fluid retention.

vii. Robergs

Robergs discloses the desire to have a blood plasma potassium level between 5 and 8 mEq/L and potassium secreted in the urine. *Robergs*, col. 2, Ins. 30-32. The potassium level in the beverage is disclosed as at least 6 mEq/L. *Id.* at col. 3, Ins. 12-13. Robergs continues to state that potassium levels as high as 50 mEq/L may be used, but there are several contraindications of using such high amounts in certain individuals. *Id.* at col. 3, Ins. 14-20.

Additionally, the use of the beverage is to address the issue of attenuation of muscle fatigue due to exercise and to prevent post-exercise fall in potassium levels. *Id.* at col. 3, Ins. 4-7. This is different than the combination of electrolytes of the present invention which promote fluid retention and voluntary fluid consumption. Furthermore, there is no motivation to combine Robergs with the other cited art. The combination of these references is merely an improper hindsight reconstruction of prior art. As such, Robergs, in combination with Fregly, Stray-Gundersen, Reference B2, Greenleaf,

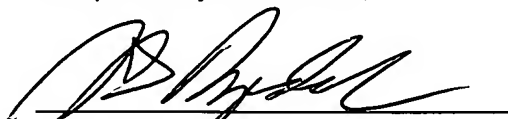
Otsuka, Fisher and Bradley, do not teach or suggest a beverage composition that aids in rehydration by stimulating voluntary fluid consumption and increasing fluid retention.

As such, the Examiner's objections have been overcome and Applicants respectfully request the rejection under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

Claims 1-184 are in condition for allowance and an early indication of allowance is solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'J. Ryndak', is written over a horizontal line.

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